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Docket No: 25401-40

PATENT

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Bonnie S Dose

IN THE UNITED STATES PATENT & TRADEMARK OFFICE

Applicant:	Magnus Ingelman-Sundberg et al	:	Confirmation No.: 8991
Serial No.:	10/532,014	:	Group Art Unit: 1642
Filing Date:	April 20, 2005	:	Examiner: Davis, Minh Tam B.

For: **The Use of Cytochrome P450 Enzyme CYP2W1 as a Drug Target for Cancer Therapy**

RESPONSE

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

In the Official Action dated April 19, 2007, the Examiner required restriction under 35 U.S.C. §§121 and 372 between:

Group 1, claims 1-3, drawn to a binding agent or an antibody to CYP2W1 or SEQ ID NO: 8;

Groups 2-4, claim 4, drawn to a method for treating lung, colon or ovarian tumor, respectively, using CYP2W1;

Groups 5-7, claim 4, drawn to a method for treating lung, colon or ovarian tumor, respectively, using CYP2W1 nucleic acid;

Group 8, claims 5-6, drawn to a method for screening for an agent that modulates CYP2W1 protein;

Group 9, claims 5-6 and 10, drawn to a method for screening for an agent that modulates CYP2W1 nucleic acid or genes regulated by CYP2W1 promoter;

Groups 10-12, claim 7, drawn to a method for treating lung, colon or ovarian cancer, respectively, using a substance activated by CYP2W1 protein;

Groups 13-15, claim 7 drawn to a method for treating lung, colon or ovarian cancer, respectively, using an inducer of CYP2W1 protein;

Groups 16-18, claim 7, drawn to a method for treating lung, colon or ovarian cancer, respectively, using binding agent of CYP2W1 protein;

Groups 19-21, claim 7, drawn to a method for treating lung, colon or ovarian cancer, respectively, using a combination of a substance activated by CYP2W1 protein and an inducer of CYP2W1 protein, and optionally a binding agent for CYP2W1 protein; and

Group 22, claims 8-9, drawn to a DNA molecule of SEQ ID NO: 10.

The Examiner asserts that the inventions of Groups 1-22 do not relate to a single general inventive concept because they lack the same or corresponding special technical feature as an antibody binding specifically to CYP2W1 protein, or SEQ ID NO: 8 is shown in Becha et al WO 2002/90521 or Asundi et al WO 2002/59260, as evidenced by Banki et al or Bendayan et al.

Specifically, the Examiner states that Becha et al disclose a polypeptide which is a human drug metabolizing enzyme that is 87% similar to SEQ ID NO: 8, from amino acid 1 to amino acid 431 and Asundi et al teach an antibody which is 75% similar to SEQ ID NO: 8, from amino acid 57 to amino acid 431. The Examiner relies on Banki et al as teaching an antibody against human transaldolase which can bind to yeast transaldolase which is about 58% homologous with human transaldolase, i.e., an antibody could cross-react and bind to a polypeptide at least with 58% homology to its antigen, and Bendayan et al as teaching that anti-human proinsulin monoclonal antibody to the Arg-Arg dipeptide, although providing very specific binding results, cross-reacts with non-related molecules, i.e., rat, bovine, procine and human glucagons.

Applicants elect the invention of Group 11, claim 7 drawn to a method for treating colon cancer using the substance activated by CYP2W1 protein. This election is made with traverse. Importantly, the Examiner has not cited any art which shows an antibody binding specifically to CYP2W1 protein or SEQ ID NO: 8. Thus, the inventions listed in Group 1-22 relate to a single general inventive concept based on a binding agent or antibody to CYP2W1 or SEQ ID NO: 8. Although the Examiner has asserted that this special technical feature is known in the art, the evidence of record does not support the Examiner's assertion. That is, the teachings of Banki et al and Bendayan et al relate to different antibodies and provide no basis for asserting any inherent binding properties in the polypeptides in either Becha et al or Asundi et al which the Examiner asserts are 87% similar and 75% similar, respectively, to SEQ ID NO: 8. Further, the Examiner has not shown that the homology of the polypeptides of Becha et al and/or Asundi et al in fact contain the necessary binding epitopes. The Examiner's assertions are clearly contrary to the understood lack of predictability in the biotechnology art.

Importantly, while the sequences of Becha et al and Asundi et al are similar to CYP2W1 in the N-terminal part of CYP2W1, namely amino acids 1-421 and 1-375, respectively, of a total

of 490 amino acids, the present specification teaches that the antibodies should be raised against the C-terminal part of CYP2W1. The Examiner's attention is directed to the present specification at page 9, lines 23-27. Further, the antibodies were shown not to be cross-reactive with other P-450 enzymes as described in the specification at page 15, lines 6-8.

In fact, claim 1 recites that the compound comprises one part conferring "specific binding affinity" towards a CYP2W1 molecule according to SEQ ID NO: 8. As noted in the art, this means that it should show substantially no binding affinity towards related proteins such as those disclosed by Becha et al and Asundi et al. Thus, the cited art does not teach the single general inventive concept of present claims 1-10 and Groups 1-22. Accordingly, reconsideration of the restriction requirement and examination of all claims 1-10 in this application is requested.

Further, as the elected Group 11 and Groups 2-7 and 10-21 are all directed to methods of treatment, and the Examiner has not shown that the methods of treatment are separately classified, it is believed that at least the methods of treatment claims 4 and 7, in their entirety, Groups 2-7 and 10-21, should be examined together. Reconsideration is respectfully requested.

It is believed that the above represents a complete response to the restriction requirement, and examination on the merits is respectfully requested.

Respectfully submitted,

By _____

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